VA MEDICAL CENTER, PORTLAND, OREGON

Medical Center
Memorandum No. 151-01

RESPONSIBLE CONDUCT OF RESEARCH AT THE VA MEDICAL CENTER

1. PURPOSE: To establish policy and procedures for conducting safe and ethical research practices at the Portland VA Medical Center (PVAMC) that promotes compliance with Federal and VA regulations and human subject rights. This MCM also establishes the Human Research Protection Program (HRPP).

2. POLICY: All research conducted at the PVAMC by PVAMC employees (full time, part time, consultant and attending, and WOC appointments) must receive Research & Development Committee approval prior to being conducted. This includes approval from all appropriate Research & Development Service subcommittees such as the Institutional Review Board (human studies), Institutional Animal Care & Use Committee (animal studies), and Subcommittee on Research Safety (biohazards/radiation studies). Publications that result from this research must be submitted to the Research & Development Committee for approval prior to publication. The publication must include the Portland VA Medical Center in the address of authors and VA support must be mentioned in a footnote or acknowledgment.

The principles governing the HRPP at the PVAMC are based on the Belmont Report and all codes of federal regulations concerning the protection of human research subjects.

3. RESPONSIBILITIES:

a. The **Director** is the Institutional Official responsible for ensuring compliance with all Federal and VA regulations governing research and is accountable for the HRPP including the protection of human research subjects.

b. The **Associate Chief of Staff for Research & Development** is responsible for:

(1) Developing, managing and evaluating policies and procedures that ensure compliance with all Federal and VA regulations governing research. This includes oversight of all aspects of the HRPP program established for human research protections.

(2)Acting as liaison between the VHA Office of Research and Development and the institution's Research and Development Committee, as well as advising the Director and VISN 20 leadership on key matters regarding research.

(3)Submission, implementation, and maintenance of an approved Federal Wide Assurance (FWA) through the medical center Director and the Office of Research Compliance and Assurance (ORCA) and to the Office for Human Research Protections (OHRP).

(4)Administration of the facility's Research and Development Programs, including the Research and Development Committee and applicable subcommittees.

(5)Financial management of the facility's Research and Development Program.

(6)Assisting investigators in their efforts to carry out VA's research mission.

(7)Developing and implementing continuous quality improvement strategies for the purpose of managing risk in the research program.

(8)Developing training requirements and insuring that these training requirements, including human, animal, and bio-safety research for investigators and members of the applicable subcommittees and staff are completed.

c. The **Research & Development Committee** serves in an advisory capacity to the Director through the Chief of Staff on the professional and administrative aspects of the research program. This oversight includes the assessment of scientific quality of research and development projects and protection of human research subjects. The Research & Development Committee is responsible for:

(1)Assuring the continuing high quality of the facility's research and development program.

(2)Planning and developing broad objectives of the research and development program so that it supports the patient care mission of the facility.

(3)Evaluating critically and deciding approval/disapproval of research with respect to the:

(a) Quality, design, desirability and feasibility of each new Research & Development proposal;

(b) Continuing Research & Development projects;

(c) Application for funding;

(d) Manuscripts to be submitted for publication; and

(e) Other reporting activities to assure maintenance of high scientific standards, protection of human subjects, adequate safety measures and proper use of animal subjects.

(4)Reviewing and declaring approval/disapproval recommendations from its subcommittees:

(a) Institutional Review Board (IRB);

(b) Institutional Animal Care and Use Committee (IACUC);

(c) Subcommittee on Research Safety; and

(d) Subcommittee on Research Space.

The Research and Development Committee will not approve any proposal that has been disapproved by any subcommittee, nor will it alter any documents or recommendations made by any subcommittees.

(5)Recommending the distribution of Research & Development funds, space, personnel, equipment, supplies, use of animal facilities and other common resources on the basis of such evaluations and after consideration of other needs. This includes an annual review of the budget assigned to the Institutional Review Board.

(6)Reviewing on an annual basis the subcommittees' Chair and members and the members' qualifications and experiences. These subcommittees include the Institutional Review Board, Institutional Animal Care and Use Committee, Subcommittee on Research Safety and the Subcommittee on Research Space.

(7)Reviews the performance reports of the IRB by utilizing continuous quality improvement strategies.

d. The **Principal Investigators** (VA employees) who are planning to conduct research at the VA Medical Center in Portland are responsible for:

(1)Submitting the following applicable forms to the Administrative Officer of Research and Development (R&D) Service at least two weeks prior to submitting a research proposal to a funding agency:

(a) Proposed Project Questionnaire (PPQ);
(b) Administrative Review forms;
(c) Project Proposal and Abstract;
(d) Institutional Review Board forms;
(e) Institutional Animal Care and Use Committee forms; and
(f) Subcommittee on Research Safety forms.

These forms may be obtained from the Research Service office.

(2) Submitting annual and continuing reviews of the research project to the R&D Service administrative office according to stated deadlines for entry into the Research & Development Information System (RDIS) database. All required reports will be submitted by the due date(s) specified by the R&D Service administrative office to comply with Federal, VACO and local requirements.

(3) Completing educational requirements and educating their staff and monitoring all safety rules and regulations in their laboratory including the requirements for annual safety training. Compliance with all requirements of the Subcommittee on Research Safety are the responsibility of each employee.

e. The **Research & Development Service Administrative Staff** assigned to the various committees and subcommittees are responsible for:

(1)Reviewing research proposal submissions, advising Principal Investigators about Federal, VACO, and local requirements for conducting research, placing research proposals on the appropriate subcommittee agenda, and coordinating the final approval by the R&D Committee.

(2)Maintaining subcommittee meeting calendars, minutes, and membership information.

(3)Assisting Principal Investigators who receive approval and funding for research projects with recruitment of research personnel, purchase of equipment and supplies, preparation of monthly budget reports, financial projections, training requirements, and assistance with day to day issues of individual research programs.

f. The **Research Assurance and Compliance Coordinator** is responsible for critically evaluating the:

(1)Institution's adherence to applicable federal regulations, state laws and accreditation standards, which govern research.

(2)Institutional Review Board's function and adherence to applicable federal regulations state laws and accreditation standards, which govern human research.

(3)Investigator's performance of human research and adherence to applicable federal regulations, state laws and accreditation standards, which govern human research.

(4)Impact of the Institution's systematic changes that impact the conduct of human research and provide information as to whether these changes have lead to improvements and for:

(5) Suggesting systematic improvements in the Institution's human research efforts that will either increase human research subject safety or improve compliance with applicable federal regulations, state laws and accreditation standards, which govern the conduct of human research.

(6) Participating, as appropriate, in the training, education and development of individuals responsible for the oversight or conduct of human research.

4. PROCEDURES:

a. **Principal Investigators must adhere to the following procedures for all research conducted at the Portland VA Medical Center:**

(1)For research projects that will be conducted at the VA Medical Center, prepare a VA Proposed Project Questionnaire and other applicable materials listed in 3.d.1 above and submit these items with the research proposal and abstract to the Administrative Officer of the Research & Development Service. The submission must be at least 2 weeks prior to the mailing deadline to allow adequate time for processing the research proposal.

(2)For research projects that will be conducted at both the VA Medical Center and Oregon Health & Science University (OHSU), prepare a VA Proposed Project Questionnaire, OHSU Proposed Project Questionnaire, and other applicable materials listed in 3.d.1 above. Submit these items with the research proposal and abstract to the Administrative Officer of Research & Development Service. VA signatures must be obtained prior to submitting the grant to OHSU Research Services. The submission must be at least 2 weeks prior to the mailing deadline to allow adequate time for processing the research proposal.

(3)Research that is conducted in hospital wards leased by OHSU and does not involve patients who are currently considered to be PVAMC in-patients must be reviewed and approved according to all applicable policies at OHSU.

(4)For research projects that will be administered and conducted only at OHSU (no VA Medical Center patients, space, supplies, nor funds will be utilized), VA Principal Investigators do not need to submit the above paperwork to the VA Research & Development Service.

(5)For research projects that will be administered by the Portland VA Research Foundation and conducted at the VA and/or OHSU, submit a VA Proposed Project Questionnaire and other applicable materials listed in 3.d.1 above and submit these items with the research proposal and abstract to the Administrative Officer of Research & Development Service. The submission must be at least 2 weeks prior to the mailing deadline to allowing adequate time for processing the research proposal.

b. The Principal Investigator must adhere to the following procedures for **research involving human subjects** at the PVAMC:

(1)Complete all required training for human subject protection prior to submitting a research protocol.

(2)Maintain credentials and privileges at the Portland VA appropriate for performing all procedures proposed in all research protocols involving human subjects submitted by the principal investigator. If the principal investigator lacks the requisite credentials and privileges, a collaborating VA clinician who is credentialed and privileged appropriately must be listed on the application. The collaborating clinician assumes responsibility for the specific procedures in question.

(3) Obtain approval from the Portland VAMC Institutional Review Board. As part of the review process, the Principal Investigator must comply with all requests for information to assess conflicts of interest.
(4)Initiate the study only **after** approval by **both** the Institutional Review Board and the Research and Development Committee. The Research and Development Committee has final responsibility of the scientific quality and appropriateness of all research involving human subjects.
(5) Adhere to all assurances given to the Institutional Review Board at the time the project was approved.
(6) Retain a copy of each signed informed consent form (VA Form 10-1086). The **original** signed consent form must be sent to the Research Service administrative office where procedures are in place to guarantee that it is scanned into the patient's electronic medical record. The original is kept on file in the R&D Service administrative office. A copy must be given to the patient and the patient must initial the original signed consent form acknowledging receipt of a copy of the informed consent form.
(7) Submit all original adverse events occurring in the study to the IRB in a timely manner.
(8) Complete annual review forms for continuing approval of ongoing research. The Research and Development Committee on an annual basis will assure the scientific quality of each active research protocol.
(9) Cite in the methods section of all manuscripts involving human studies at the PVAMC that the PVAMC IRB approved the project.

c. The Principal Investigator must adhere to the following procedures for **research involving animal subjects** at the PVAMC:
(1)Obtain approval from the VA Institutional Animal Care and Use Committee (IACUC).
(2)Complete continuing review forms for approval of ongoing research and indicating research results, changes in protocol, and completion and termination of the research.
(3)Cite in the methods section of all manuscripts involving animal studies at the PVAMC that the PVAMC IACUC approved the project.

d. The Principal Investigator must adhere to the following procedures for **research involving biohazards and/or radioactive materials** at the PVAMC:
(1)Obtain approval for all new grant applications from the VA Subcommittee on Research Safety.
(2)Complete an annual self-inspection survey and passing an inspection conducted by a member of the Subcommittee on Research Safety.
(3)Obtain an "Authorized Users License" which is issued by the Radiation Safety Subcommittee and authorizes the use and purchase of isotopes.

5. REFERENCES:
M-3, Part I, Chapters 3, 4, 8, 9, 11, and 12
Portland IRB Policy and Procedure Manual
Portland IACUC Policy and Procedure Manual
Belmont Report

21CFR50 *Protection of Human Subjects*
21 CFR56 *Institutional Review Boards*
38CFR16 *Protection of Human Subjects*
45CFR46 *Common Rule*
NCQA Accreditation Standards

6. CONCURRENCES:
Chief, Quality & Performance Service (P3Q&P)
R&D Committee (R&D)
Chief of Staff (P3CCE)

7. RESCISSION: Medical Center Memorandum No. 151-1, November 1, 2001

8. FOLLOW-UP RESPONSIBILITY: ACOS Research & Development Service (R&D)

9. REVIEW DATE:

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Medical Center Director

Distribution: A & D